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Bate of Deposit: December 16, 2008

Attorney Docket No. 24852-501 CIP

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

cation Number:

10/600,132

Confirmation No.: 8627

TRADEA pplicant

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Thomas A. MILLER

Filed

DEC 16 2008

June 19, 2003

TC/A.U.

1621

Examiner

Yevgeny VALENROD

For

POLYMORPHS OF SUBEROYLANILIDE

**HYDROXAMIC ACID** 

#### MAIL STOP PATENT EXT.

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

# TRANSMITTAL LETTER

Transmitted herewith for filing in the present application are the following documents:

- 1. Application for Patent Term Adjustment under 37 C.F.R. § 1.705(d) (4 pages);
- 2. Exhibit A (Supplemental Information Disclosure Statement) accompanying the Application for Patent Term Adjustment (1 page);
- 3. Check No. 4724 in the amount of \$200.00 for the Application Filing Fee; and
- 4. Return postcard.

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (212) 935-3000.

No additional fees are believed to be due; however, the Commissioner is authorized to charge such fee, or credit any overpayment in fees to Deposit Account No. 50-0311, Customer Number 35437, Attorney Docket No. 24852-501 CIP.

Respectfully submitted,

Dated: December 16, 2008

Ivor R. Elrifi, Reg. No. 39,529
Muriel M. Liberto, Reg. No. 55,382

Muriel M. Liberto, Reg. No. 55,382 Michelle A. Iwamoto, Reg. No. 55,296

Attorneys/Agent for Applicant c/o MINTZ, LEVIN, et al. 666 Third Avenue-24<sup>th</sup> Floor New York, New York 10017 Telephone: (212) 935-3000

Telefax: (212) 983-3115

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## APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(d)

Sir:

The above-identified application issued on November 25, 2008. The total patent term adjustment calculated by the Patent Office for this application is 1,351 days. Applicant hereby respectfully requests reconsideration of the patent term adjustment for this application. Specifically, Applicant believes that the total patent term adjustment should be **1,468** days.

In support of this request, Applicant submits the following statement of facts pursuant to 37 C.F.R. § 1.705(b).

(i) The correct patent term adjustment calculated under 37 C.F.R. § 1.702(a) is <u>578</u> days. In response to Applicant's request for review of the patent term calculation under § 1.705(b), the Office determined that the correct term was <u>604</u> days, as set forth in the Letter Regarding Patent Term Adjustment mailed by the Office on September 2, 2008. However, Applicant believes that, under the rule announced in *Wyeth v. Dudas* and discussed in more detail below, to eliminate the overlap between the administrative delay and the 3-year maximum pendency delay, the 604 days should be <u>reduced by 26 days</u> of administrative delay that

occurred during the time period under 37 C.F.R. § 1.702(b), *i.e.*, the time from when the patent should have issued (three years from its filing date) to the date it actually issued, which is the period from June 19, 2006 to November 25, 2008. The administrative delay occurred due to the delay in mailing the Notice of Allowance under § 1.702(a)(2).

- (ii) The correct patent term adjustment calculated under 37 C.F.R. § 1.702(b) is <u>890</u> days, due to the failure of the Office to issue a patent within three years after the date on which the application was filed. This application was filed on June 19, 2003. Accordingly, the application should have issued three years later, on June 19, 2006. However, the actual issue date was November 25, 2008, which is a delay of 890 days.
- (iii) Applicant notes that the Office calculated an additional 21 days of delay attributable to Applicant under 37 C.F.R.§ 1.704, which were not included in the calculation of the 604 days under 37 C.F.R.§ 1.702(a) noted above. This 21 days was apparently due to Applicant's filing of a Communication after Notice of Allowance on August 1, 2008, to which the Office responded on August 21, 2008. However, Applicant notes that this Communication was filed to correct an error in the Office's previous calculation of the patent term adjustment, which had omitted the delay due to Applicant's filing of an Information Disclosure Statement on July 19, 2007. Accordingly, Applicant does not believe that the filing of this Communication should have been counted as a delay under § 1.704.

In addition, Applicant believes that the 48 days counted as Applicant's delay for the filing of an Information Disclosure Statement ("IDS") on September 18, 2008, is in error because that IDS was filed within 30 days of the receipt of the information in the IDS from a foreign patent office. A statement to that effect was included in the IDS letter, a copy of which is submitted herewith as **Exhibit** A.

(iv) The adjustment sought under 37 C.F.R.§ 1.703(f) is the sum of the periods under § 1.702(a)(578 days) and § 1.702(b)(890 days), less the additional delays

attributable to Applicant (0 days). Accordingly, Applicant respectfully requests an adjustment of patent term under § 1.703(f) to indicate a total PTA of 1,468 days.

In support of Applicant's request for the adjustment under § 1.703(f) to include the sum of the periods under 1.702(a) and § 1.702(b), rather than the greater of these two periods, Applicants rely on the decision of the U.S. District Court for the District of Columbia in Wyeth v. Dudas, Civil Action No. 07-1492 (D.D.C. September 20, 2008). In that decision, the Court construed the meaning of the statutory provision regarding the limitations on extensions granted for delays under 35 U.S.C. § 154(b)(1)(A-C):

(A) In general. -- To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

35 U.S.C. § 154(b)(2)(A). The court stated that "[t]he operative question under 35 U.S.C. § 154(b)(2)(A) is whether periods of delay attributable to grounds specified in paragraph (1) overlap." See Memorandum Opinion at p. 8. (internal quotations omitted). In the opinion of the district court, "[t]he only way that periods of time can "overlap" is if they occur on the same day." Id. The court thus rejected the Patent Office's view that any administrative delay under 35 U.S.C. § 154(b)(1)(A) ("A delays") overlaps with any 3-year maximum pendency delay under 35 U.S.C. § 154(b)(1)(B) ("B delay"). In the district court's view, the only A delays which overlap with the B delay are those which occur after the B period begins, which is when the Patent Office has failed to issue a patent within three years of an application's filing date, and not before. See Memorandum Opinion at p. 5-6, 9.

Applying the rule in Dudas to the present facts, the period for A delays ends on June 19, 2006, which is three years from the filing date of this application, June 19, 2003. The period for B delay begins on June 20, 2006 and ends on the date of issuance of the patent, November 25, 2008, a period of 890 days. Accordingly, the total patent term adjustment should be calculated from the sum of the non-overlapping A and B periods (578+890) days, less the delays due to applicant during the B period, 0 days, giving a total of 1,468 days.

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Applicant notes that the above-identified application is not subject to a terminal

disclaimer.

In summary, Applicant respectfully requests an adjustment of patent term under 37 C.F.R.

§ 1.703(f) to indicate a total PTA of 1,468 days.

Pursuant to 37 C.F.R. § 1.705(d) and § 1.18(e), the fee required for filing this application

for patent term adjustment is \$200.00. Enclosed is Check No. 4724 in the amount of \$200.00 as

required under § 1.18(e).

No additional fees are believed to be due; however, the Commissioner is authorized to

charge such fee, or credit any overpayment in fees to Deposit Account No. 50-0311, Customer

Number 35437, Attorney Docket No. 24852-501 CIP.

Date: December 16, 2008

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Yevgeny VALENROD

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For

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#### MAIL STOP ISSUE FEE

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

#### SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

In accordance with MPEP §609.05(b), Applicants respectfully request the Examiner place a copy of the document listed on the attached modified Form PTO-1449 in the abovereferenced application, a copy of which is submitted herewith.

This Supplemental Information Disclosure Statement is being filed after the mailing date of a Notice of Allowance and payment of the Issue Fee.

Applicants hereby certify, as specified in 37 C.F.R. §1.97(e), that the item of information contained in this Supplemental Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than thirty (30) days prior to the filing of this Supplemental Statement. No fee is required.

Please charge any fees that may be due, or credit any overpayment of same, to Deposit Account No. 50-0311, Reference No. 24852-501 CIP, Customer No. 35437.

Respectfully submitted,

Dated: September 18, 2008

michelle & swamsto

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